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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,521	09/14/2004	Jean Berthier	258409US0X PCT	6722

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EXAMINER
WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
1637	

NOTIFICATION DATE	DELIVERY MODE
12/02/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/507,521	BERTHIER ET AL.	
	Examiner	Art Unit	
	CYNTHIA B. WILDER	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/9/2008 has been entered. Claims 1-19 have been canceled. Claims 20-38 have been added and are pending in the instant application. Accordingly, the previous rejections of the claims are withdrawn in view of Applicant's cancellation of the claims. Applicant's amendment necessitates the new grounds of rejections presented below.

New Grounds of Rejections

Claim Interpretation

The claim 20 recites the limitation the limitation wherein the interface layer "fixes the macromolecules or agglomerate". Neither the specification nor claim provides a limitation for the term "fixes". Thus, for the purpose of application of prior art, the term "fixes" is being interpreted as "stabilizes" or "retain".

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 20, 22, 23, 25, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Lockwood et al (Pharmaceutical Research, vol. 14, no. 11, 1997). Regarding claims 20, 22, 23, 25, 33 and 35, Lockward et al teach a method for concentration of a macromolecule in a liquid sample, the method comprising: providing a liquid medium, the liquid medium comprising the liquid sample and an interface layer, wherein the interface layer located on the surface of the liquid sample, fixes the macromolecule and has a small volume as compared to liquid sample, forming a stabilized dispersion form by injection directly in the liquid sample of gaseous streams to form an interstitial medium constituting the foam; and resorbing the dispersion to reform the interface layer by drainage of the interstitial medium constituting the foam , wherein the macromolecule is enriched or concentrated in the interface layer which is collected as the foamate (see entire reference, such as e.g., abstract and sections entitled "The Foam Fractionation process" at pages 1511 and 11512 and "solution conditions and operational parameters at page 1513). Lockwood teaches wherein the macromolecule is protein (abstract) and wherein the method allows for enrichment, purification and detection (see pages 1512 and 1513). Therefore, Lockwood meet the limitations of the claims above.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 21, 24, 26, 27-38 are rejected under 35 U.S.C. 103(a) as being unpatentable Lockwood et al (Pharmaceutical Research, vol. 14, no. 11, 1997) and Lalchev et al (Biotechnology and Bioengineering, vol. XXIV, pages 2253-2262, 1982) in view of Ijiro et al (citation made of record). Regarding claims 24, 26, 27-28, Lockwood et al teach a method for enriching a macromolecule in a liquid sample, the method comprising: providing a liquid medium, the liquid medium comprising the liquid sample and an interface layer, wherein the interface layer located on the surface of the liquid sample, fixes the macromolecule and inherently has a small volume as compared to liquid sample, forming a stabilized dispersion form by injection, directly in the liquid sample of gaseous streams to form an interstitial medium constituting the foam; and resorbing the dispersion to reform the interface layer by drainage of the interstitial medium constituting the foam , wherein the macromolecule is enriched or concentrated in the interface layer which is collected as the foamate (see pages 15111-1513).

Lockwood et al teaches wherein the macromolecule is protein, which inherently encompasses the teaching of prions, which are protein molecules (e.g., abstract).

Lockwood et al do not teach wherein the macromolecule is DNA.

Lockwood et al however teaches that the method of foam fractionation can be used to separate DNA and protein (see bottom of page 1512, col. 2 bridging page 1513, col. 1). Lockwood cites Lalchev et al to support this assertion. Lalchev et al teach the successful use of foam fractionation to separate DNA and protein (see e.g., abstract and pages 2254 and 2255).

Lockwood in view of Lalchev et al do not teach wherein the method comprises specific means of fixing the macromolecule as required in the claims.

Ijiro et al. teach a method comprising forming a stabilized dispersion of an emulsion type from a medium comprising said liquid sample and an interface layer,, wherein said interface is a gas-liquid interface, such as taught by Lockwood et al, said interface layer capable of fixing macromolecules (col. 2, lines 46-60; col. 3, line 35 to col. 4, line 61). Ijiro teaches wherein the fixing of the macromolecule is by chemical affinity ((col. 2, lines 46-60; col. 3, line 35 to col. 4, line 61). Ijiro et al teaches wherein the macromolecule is DNA (col. 3, lines 55-56). Likewise, Ijiro et al teaches wherein the macromolecule is DNA and the molecule capable of fixing the DNA is functionalized with a probe to allow specific hybridization of the DNA or an intercalator (col. 3, line 54 to col. 4, line 13).

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention that one of ordinary skill in

the art could obtain predictable results of enriching DNA or protein using the known methods of foam/emulsion fractionation as taught by Lockwood et al in view of Lalchev et al and Ijiro et al. On of ordinary skill in the art at the time of the claimed invention would have been motivated to utilize foam/emulsion fractionation for the purpose of enriching nucleic acids or proteins or collidal particles based on the advantages taught by Lockwood that foam fractionation has the potential to be a cost-effective component of purification/enrichment schemes (see abstract).

With regards to the claims 21, 29-32, these claims merely recite a plethora of conventional nucleic acid manipulation reagents and methodologies, as well as well as routine optimization of reaction components, concentrations, and parameters as evidence by Ijiro et al. Clearly such conventional and trivial modification and optimizations do not contribute towards patentability. Thus, one of ordinary skill in the art at the time of the claimed invention would have been motivated to modify the primary references in the manner of the claims to achieve the expected benefits, optimizations an/or expanded applications. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods using different means of mixing and fixing the DNA as claimed for the obvious benefit of detecting specific hybridization or for the benefit of controlling or detecting the orientation of the nucleic acid as taught by Ijiro et al (col. 7). The combination of Lockwood et al in view of Lalchev et al and Ijiro et al is *prima facie* obvious in the absence of secondary consideration.

Regarding claims 35-38, Lockwood et al in view of Lalchev et al and further in view of Ijiro et al teach a method of enrichment/purification of a macromolecule, wherein the macromolecule is DNA or protein. Ijiro et al teach wherein the DNA is further used in hybridization reactions. The references do not teach wherein the DNA (macromolecule) is used in amplification reaction. However, it would have *prima facie* obvious to the ordinary artisan at the time of the claimed invention that the enriched or purified DNA or protein could be used in any of the plethora of well known biochemical reactions, such as nucleic acid amplification, sequencing, hybridization and etc. As noted earlier, these claims merely recite a plethora of conventional nucleic acid manipulation reagents and methodologies, as well as well as routine optimization or reaction components, concentrations, and parameters. Clearly such conventional and trivial modification and optimizations do not contribute towards patentability. Thus, one of ordinary skill in the art would have been motivated to modify the primary references in the manner of the claims to achieve the expected benefits, optimizations an/or expanded applications. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods in the absence of secondary consideration.

Conclusion

7. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CYNTHIA B. WILDER whose

telephone number is (571)272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia B. Wilder/
Examiner, Art Unit 1637